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13	UNITED STATES DISTRICT COURT FOR THE	
14	NORTHERN DISTRICT OF CALIFORNIA	
15	MOLLY BROWN, PARSA MILLER, and	CASE NO. 4:21-CV-05132-HSG
16	LAUREN MORGAN, as individuals, on behalf of themselves, the general public and those similarly situated,	PLAINTIFFS' OPPOSITION TO DEFENDANT'S ADMINISTRATIVE
17	Plaintiffs,	MOTION FOR LEAVE TO FILE NOTICE OF SUPPLEMENTAL AUTHORITY
18	V.	
19	NATURE'S PATH FOODS, INC.,	
20	Defendant.	
21	Defendant.	
22	The Local Rules in the Northern District of California typically do not allow litigants to	
23	submit supplementary authority after the Court takes a motion under submission. See Local Rule	
24	7-3(d). When they do allow supplementary authority, it is permitted only for other judicial	
25	opinions absent special leave. See Local Rule 7-3(d)(2). Nature's Path's request is improper	
26	because it is not a relevant judicial opinion and comes after the Court took the motion under	
27	submission.	
28	In any event, the FDA webpage supports Plaintiffs' position. It confirms that under	

PLS.' OPP. TO DEF.'S ADMIN. MTN. FOR LEAVE TO FILE SUPP. AUTHORITY

Section 101.13(o), PDCAAS can be used to calculate grams of protein to "determine compliance" for an otherwise authorized front label protein content claim (directly contrary to Nature's Path's argument in its initial brief). But neither Section 101.13(o) nor this website guidance state what protein claims Section 101.13(i)(3)—the key regulation—actually authorizes Nature's Path to place on its front labels. That section provides that Nature's Path can state the "amount or percentage" of a nutrient, such as protein, only if doing so is "not false or misleading in any respect." And the FDA has already expressly stated in published guidance that "protein quantity alone [i.e., a number based solely on nitrogen testing] can be misleading on foods that are of low protein quality" for the exact same reasons plaintiff has alleged in the complaint, i.e., not all of that protein is actually available to support the human body's protein needs. 58 Fed. Reg. 2079 at 2101-2 (emphases added). Accordingly, Section 101.13(i)(3) requires Nature's Path to do one of three things to avoid stating a misleading amount of protein: (1) make a protein claim based solely on the PDCAAS method; (2) make a protein claim based on a combination of the nitrogen and PDCAAS methods; or (3) do not make a protein claim at all. This FDA guidance confirms that section 101.13(o) can determine compliance for any one of those three non-misleading options.

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Dated: January 24, 2022

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